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110TH CONGRESS
1ST SESSION

H. R. 3140

To amend title XIX of the Social Security Act to ensure and foster continued beneficiary access to generic drugs under the Medicaid Program by setting pharmacy reimbursement based on retail acquisition cost and to promote the use of generic drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 24, 2007

Mrs. BOYDA of Kansas (for herself, Mr. WEINER, Mrs. EMERSON, Mr. ADERHOLT, Mr. ALEXANDER, Mr. BERRY, Mr. BONNER, Mr. BOREN, Mr. BOUCHER, Mr. BOUSTANY, Mr. BRALEY of Iowa, Mr. CARNEY, Mr. CUMMINGS, Mr. DAVID DAVIS of Tennessee, Mr. DAVIS of Kentucky, Mr. ETHERIDGE, Mr. FARR, Mr. GORDON of Tennessee, Mr. HIGGINS, Mr. JONES of North Carolina, Mr. LOBIONDO, Mr. LOEBSACK, Mr. MOORE of Kansas, Mr. MORAN of Kansas, Mr. ORTIZ, Mr. ROGERS of Alabama, Mr. ROSS, Mr. SKELTON, Mr. TIAHRT, and Mr. WALZ of Minnesota) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XIX of the Social Security Act to ensure and foster continued beneficiary access to generic drugs under the Medicaid Program by setting pharmacy reimbursement based on retail acquisition cost and to promote the use of generic drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Saving Our Community Pharmacies Act of 2007''.

SEC. 2. USING MEDIAN RETAIL ACQUISITION COST AS BASIS FOR MEDICAID REIMBURSEMENT LIMITS ON GENERIC DRUGS.

(a) IN GENERAL.—Subsection (e) of section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by striking paragraph (5) and inserting the following:

''(5) APPLICATION OF FEDERAL UPPER PAYMENT LIMITS.—

''(A) CONTINUED USE OF AWP.—Effective January 1, 2007, and until subparagraph (B) is in effect, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall continue to apply the methodology in effect before the date of the enactment of the Deficit Reduction Act of 2005.

''(B) USE OF MEDIAN RETAIL ACQUISITION COST.— Effective on the first day of the second quarter that begins after the date of the enactment of the Saving Our Community Pharmacies Act of 2007, in applying the Federal upper reimbursement limit under paragraph (4)

and section 447.332(b) of title 42 of the Code of Federal Regulations (as in effect but for subparagraph (A)), the Secretary shall substitute the median retail acquisition cost (as computed under subparagraph (C)) for the published price.

''(C) COMPUTATION OF MEDIAN RETAIL ACQUISITION COST.—

''(i) SMOOTHING AND TRANSITIONS.—Except as otherwise provided in this subparagraph, the Secretary shall calculate the median retail acquisition cost for a multiple source drug subject to a Federal upper limit for months in a calendar quarter by computing the median of the retail acquisition costs (as defined in subsection (k)(10)) over the 4-calendar-quarter period ending with the second preceding calendar quarter.

''(ii) LIMITATION ON SALES TO BE COUNTED.—In computing the median retail acquisition cost for a drug, the Secretary shall not take into account sales other than sales to community retail pharmacies and shall not include the following:

''(I) Sales to mail order facilities.

''(II) Prices paid under a State supplemental program, State only program, or a State Pharmacy Assistance Programs (SPAP).

''(iii) TRANSITION FOR FIRST IMPLEMENTATION.—For the first 4 calendar quarters in which subparagraph (B) is in effect, subject to clause (iv), in calculating the median retail acquisition cost for all drugs the Secretary shall only use the retail acquisition costs for those quarters beginning with the last calendar quarter that began before the date of the enactment of this paragraph for which data are released.

''(iv) TRANSITION FOR DRUGS NEWLY QUALIFYING AS MULTIPLE SOURCE.—In the case of a drug product for the first four calendar quarters in which it qualifies as a multiple source drug, in calculating the median retail acquisition cost for the drug the Secretary shall only use the retail acquisition costs for the drug beginning with the first such quarter for which data are collected.''.

(b) DEFINITION OF RETAIL ACQUISITION COST AND RELATED DEFINITIONS.—Subsection (k) of such section is amended by adding at the end the following new paragraph:

''(10) RETAIL ACQUISITION COST AND RELATED DEFINITIONS.—

''(A) RETAIL ACQUISITION COST.—The term 'retail acquisition cost' means, for a multiple source drug furnished, the costs of community retail pharmacies (as defined in subparagraph (D)) to obtain the drug, as determined under subsection (f)(5).

''(B) ITEMS NOT INCLUDED IN RETAIL ACQUISITION COST.—In computing the retail acquisition costs for a drug, the following shall not be taken into account:

''(i) Discounts, rebates, and price concessions to pharmacy benefit managers.

''(ii) Non-contingent free goods.

''(iii) Patient assistance programs, such as specialty services for cancer treatment.

''(iv) Administrative service agreements.

''(v) Inventory management fees.

''(vi) Fee-for-service agreements to wholesalers.

''(vii) Adjustments that reduce the actual price realized, except to the extent that they are not reflective of purchasing costs of retail pharmacies.

''(viii) Costs of other classes of trade not reflective of retail pharmacy purchasing costs.

''(ix) Prompt pay discounts extended to retail community pharmacies.

''(C) ITEMS TAKEN INTO ACCOUNT IN DETERMINING RETAIL ACQUISITION COST.—In computing the retail acquisition cost for a drug, the Secretary shall take into account the following:

''(i) Volume (or comparable discounts) discounts, chargebacks, and allowances for free goods contingent on purchase requirements, to the extent actually paid or credited to the retail pharmacy. Discounts that may be paid in a calendar quarter for an aggregate purchase of generic drugs, applied to each drug in proportion to the percentage purchased.

''(ii) An estimate of the rebates and discounts that may be earned by retail community pharmacies but not credited in the time period in which the average retail acquisition cost is calculated for each drug in the survey, as determined in accordance with a methodology specified by the survey contractor after consultation with the affected stakeholders.

''(iii) In the event of a reduction in the acquisition price of a drug by a manufacturer where that manufacturer issues a credit to the pharmacy to lower the cost of existing inventory to the new acquisition price, such credit shall be applied to the existing inventory, acquired at the higher cost, to lower the cost basis of that existing inventory and such lower cost basis shall be the acquisition price for such inventory in any price reported.

''(iv) With respect to drugs dispensed by pharmacies that own and operate their own warehouse distribution systems, insofar as the retail acquisition costs takes into account the costs associated with the own-

ership and operation of such distribution system, such costs shall be a fixed percentage of the average wholesaler markup, as promulgated each year by the Secretary.

''(D) COMMUNITY RETAIL PHARMACY.—The term 'community retail pharmacy' means a traditional independent, chain, mass merchandise, or supermarket pharmacy.

''(E) PHARMACY BENEFITS MANAGER.—The term 'pharmacy benefits manager' means an entity that contracts with a managed care organization, self-insured company, or government program to provide a range of pharmacy management benefit services, including pharmacy network management, drug utilization review, outcomes management, and disease management.

''(F) WIDELY AVAILABLE.—The term 'widely available' means, with respect to a multiple source drug, that the drug is available for purchase by retail community pharmacies throughout the nation from at least two national wholesalers.''.

(c) SURVEYS OF COMMUNITY RETAIL PRICES.—Subsection (f) of such section is amended by adding at the end the following new paragraph:

''(5) SURVEYS FOR DETERMINING COMMUNITY RETAIL PRICES FOR MULTIPLE SOURCE DRUGS.—The following rules apply to the determination of retail acquisition costs for multiple source drugs for purposes of computing the median retail acquisition cost under subsection (e)(5):

''(A) IN GENERAL.—The Secretary shall conduct national surveys on a quarterly basis of community retail pharmacies using the criteria described in such subsection to determine retail acquisition costs for all multiple source drugs. The first such survey shall be for the calendar quarter in which Saving Our Community Pharmacies Act of 2007 is enacted.

''(B) SAMPLE.—Each such survey shall consist of a randomly selected sample that—

''(i) represents at least 5 percent of the community retail pharmacies; and

''(ii) contains a representative percentage of business among the types of community retail pharmacies, including

independent, chain, mass merchandise, and supermarket pharmacies.

''(C) SURVEY INFORMATION.—The cost surveys shall include surveys of the elements used in computing retail acquisition costs, including those items excluded (or included) in computing such costs under subparagraphs (B) and (C) of subsection (k)(10). In completing the cost surveys and disclosing other information under this section, retail community pharmacies may make reasonable assumptions and interpretations that are reasonably consistent with the terms of this section.

''(D) TREATMENT OF PHARMACIES UNDER COMMON OWNERSHIP OR PURCHASING ARRANGEMENTS.—In the case of retail community pharmacies that purchase a multiple source drug through common ownership, management, or other arrangements, such pharmacies shall report the average price paid for the multiple source drug across all pharmacies operating under such common ownership, management, or arrangement.

''(E) CONFIDENTIALITY.—The information disclosed in response to surveys under this

paragraph is confidential and the Secretary (or any contractor therewith) shall not disclose such information in a form which discloses the identity of a specific pharmacy or company, or the retail acquisition costs for multiple source drugs of such a pharmacy or company, except—

''(i) as the Secretary determines to be necessary to carry out this section;

''(ii) to permit the Comptroller General to review the information provided;

''(iii) to permit the Director of the Congressional Budget Office to review the information provided; and

''(iv) to the Secretary to disclose (through a website accessible to the public) median retail acquisition costs.

The Secretary shall post on a public Federal website for the Medicaid program (and otherwise make available to States) the median retail acquisition costs for multiple source drugs.

''(F) CONTRACTOR BIDDING.—The Secretary shall provide for surveys under this paragraph to be conducted through a contract with a qualified entity. In contracting for such serv-

ices, the Secretary shall competitively bid for an outside vendor in accordance with the Federal Acquisition Regulations. The Secretary shall consult with retail community pharmacies during the process of developing a request for proposals, receiving and reviewing bids, and contracting with such a vendor. Any contract entered into as part of this bidding process shall require the successful bidder to keep confidential and not disclose to any other Federal agency or other third parties, including State agencies, all survey responses and any other disclosure made by a retail community pharmacy under this section.

''(G) AUDITING.—If the Secretary has reasonable cause to believe that a survey response submitted by a retail community pharmacy is not complete or accurate, the Secretary may conduct an audit of the records used by the retail community pharmacy to develop that survey response. In conducting such inspection the Secretary may require a retail community pharmacy to produce for inspection, consistent with subparagraph (C), only the records actually relied upon by the retail community pharmacy in

completing the survey. Retail community pharmacies shall retain such records for one year, and the Secretary shall not commence an inspection of records related to a survey response more than one year after the survey response was submitted by a retail community pharmacy.

''(H) PENALTY FOR FAILURE TO COOPERATE IN AUDIT FOR PROVISION OF FALSE INFORMATION.—The Secretary may impose a civil monetary penalty on a retail community pharmacy, if the pharmacy refuses a request by the Secretary for information in connection with an audit under subparagraph (G) or knowingly provides false information in such an audit or in a survey under this paragraph. The amount of such penalty shall not exceed $10,000 in the case of such a refusal or $10,000 for each item of false information provided. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).''.

SEC. 3. ENCOURAGING GENERIC UTILIZATION AND OTHER EVIDENCE-BASED COST CONTROL PROGRAMS UNDER THE MEDICAID PROGRAM.

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is further amended by adding at the end the following new subsection:

''(l) ESTABLISHMENT OF EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM.—

''(1) IN GENERAL.—In order to control costs without reducing the quality of care when providing payment for covered outpatient drugs. under the State plan under this title, each State agency shall establish and implement (beginning with the second calendar quarter that begins after the date of the enactment of this subsection), an evidence-based prescription drug program in accordance with paragraph (3). Each such program shall be designed in a manner so as to result in a generic dispensing rate for a fiscal year (or, in the case of implementation after the beginning of a fiscal year for the remainder of such fiscal year) that is at least the target generic dispensing rate specified in paragraph (2) for the State and fiscal year (or portion thereof) involved. The Secretary is authorized to reduce the Federal financial participation under this title for quarters in the fiscal year with respect to covered outpatient

drugs to such amount as would reflect the State's achievement of such a target generic dispensing rate for such quarters and drugs.

''(2) TARGET GENERIC DISPENSING RATE.—The target generic dispensing rate for a State for a fiscal year (or portion thereof) is the lesser of—

''(A) 65 percent; or

''(B) in the case of—

''(i) a State with a generic dispensing rate for the previous fiscal year that is below the national average of such rate for such fiscal year, 3 percentage points above rate for the State in the previous fiscal year; or

''(ii) any other State, at least 1 percent point above such rate for the State in the previous fiscal year.

''(3) REQUIREMENTS.—Each such program shall—

''(A) prohibit reimbursement for covered outpatient drugs that are determined to be ineffective by the Commissioner of Food and Drugs;

''(B) adopt rules in order to ensure that less expensive generic drugs will be used in as

many cases as possible with approval of the physician;

''(C) consider the use of drugs with lower abuse potential in substitution for drugs with significant abuse potential; and

''(D) establish an independent pharmacy and therapeutics committee to evaluate the effectiveness of covered outpatient drugs in the development of such program.

''(4) GENERIC DISPENSING RATE.—For purposes of this subsection, the term 'generic dispensing rate' means, with respect to a multiple source drug, the proportion of the total volume of such drugs dispensed, that are generic drugs.''.

SEC. 4. CHANGES TO DEFINITION OF MULTIPLE SOURCE DRUG AND APPLICATION TO UPPER PAYMENT LIMITS.

(a) IN GENERAL.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is further amended—

(1) in subsection (e)(4)—

(A) by striking ''each multiple source drug'' and inserting ''each widely available multiple source drug''; and

(B) by striking ''(or effective January 1, 2007, two or more)''; and

(2) in subsection (k)(7)(A)(i)—

(A) in the matter before subclause (I), by striking ''1 other drug product'' and inserting ''2 other drug products''; and

(B) in each of subclauses (I), (II), and (III), by striking ''is'' and inserting ''are''.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the first day of the second calendar quarter beginning after the date of the enactment of this Act.

SEC. 5. GAO STUDY OF COMMUNITY PHARMACY DISPENSING COSTS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the costs of community retail pharmacies to dispense prescription drugs.

(b) REPORT.—Not later than one year after the date of the enactment of this Act, the Comptroller General shall submit a report to Congress on the study conducted under subsection (a).

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